

REMARKS

The present application contains claims 1-89.

Obviousness-Type Double Patenting Rejection

Claims 1-81, 83 and 84 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-80 of copending Application No. 10/048,803. Applicants are prepared to file a terminal disclaimer in compliance with 37 CFR 1.321(c), as the applications in question are commonly owned. However, the terminal disclaimer will not be filed at this time since this is a non-final rejection and the claims of one or both applications may possibly change during prosecution.

Obviousness Rejection

Claims 1-89 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,949,081 to *Chance* in view of US 5,445,609 to *Lattin et al.* and further in view of US 5,026,397 to *Aoki et al.* Applicants respectfully disagree with this rejection. The Examiner has failed to establish a *prima facie* case for obviousness because, even in combination, the references do not teach every limitation of the independent, and thus dependent, claims. Furthermore, there is no suggestion or motivation to combine *Chance* and/or *Lattin* with *Aoki* in order to create the Applicants' invention.

None of the cited references describe a control effect. Therefore, even in combination, *Chance*, *Lattin*, and *Aoki* do not teach all of the limitations of the rejected claims. A control effect in the context of the present application describes using a signal for controlling activity of at least part of a heart. *Chance* describes only sensing of some function of the heart, such as heart rate, but does not teach or suggest using any signal for controlling the activity of the heart. *Chance* indicates that drug delivery can be achieved using a device such as that described in *Lattin*. However, *Lattin* primarily concentrates its description on the structure of its disposable electrode and does not teach or suggest control signals for controlling any activity of the heart. The third cited reference, *Aoki*, also does not describe using any control signals, but rather describes electrocardiogram sensing only with respect to the heart. Because none of the cited references even contemplate control signals, there cannot possibly be any anticipation or nonobviousness of claims which recite a control effect. In other words, a combination of these three references does not establish a *prima facie* case for obviousness as not all the limitations of the claims are taught or suggested.

In addition, none of the cited references teach or suggest an electric field having a non-excitatory effect. The section of *Lattin* to which the Examiner relates, column 1, lines 33-34, bears

no relation to the (non)excitatory nature of the control effect, but rather to the ionization of the agent being transported. Examples of non-excitatory control signals, and their utility for rendering treatment to a patient, appear in the present application on pages 25 and 26.

Additionally or alternatively, there is no motivation or suggestion to combine the cited references in order to provide the presently claimed invention. While *Chance* describes an apparatus for sensing effects of a drug on a patient, and modifying delivery of the drug based on the sensing, it is clear that the *Chance* invention is intended for external use only (see Fig. 1). In addition, *Lattin* also seems to be designed for external use, as it is referenced by *Chance* as a suitable drug delivery device, and since it includes grasping handles which are intended to be grasped by the user of the device. It is presumed that a user would not be able to use the grasping handles if it was inside the user's body. In addition, considering the grasping handles are adapted to be grasped by the fingers of a user of the *Lattin* device, it would appear that the electrodes described in *Lattin* are not suitably sized for internal use. Neither of these two references describes or suggests using an invasive sensing and/or transport device and therefore, no motivation exists to combine the two to create one.

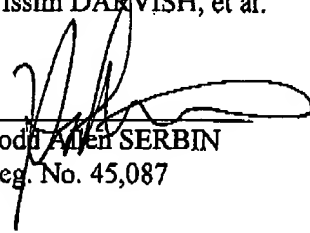
Furthermore, there is no suggestion to combine either *Chance* or *Lattin* with the teachings of *Aoki*, since it would appear from *Chance* and *Lattin* that they are designed to provide drug transport devices which are used non-invasively. *Aoki*, however, is intended to be at least transcutaneously implantable in order to provide drug transport. Notwithstanding this, the electrodes of *Lattin* are not provided with appropriate means for functioning as pacing electrodes and therefore would not be used by someone skilled in the art in combination with the teachings of *Aoki* to provide pacing as suggested by the Examiner. For example, there is no description in *Lattin* regarding signal frequencies operative to achieve pacing. As another example of why *Lattin* is not obvious to use for pacing, there is no provision in *Lattin* for meeting the electrical power needs that are typically required of pacing electrodes.

The dependent claims are patentable at least for their dependence on patentable independent claims 1, 70, 75, 82, 83 and 85. It is noted, however, that at least some of the dependent claims, in addition to those indicated by the Examiner as being allowable, add further patentability over the independent claims. Claim 43, for example, requires that the control effect is selected to prevent an adverse effect of the transport pulse. Claim 44, for example, requires that the control effect is selected to prevent an adverse effect of the molecule. Claim 46, for example, requires that the control effect is selected to counteract an adverse effect of the molecule. Claim 47, for example, requires that the control effect is selected to prepare the tissue for the transport.

Claim 48, for example, requires that the control effect is selected to extend a period of time suitable for provision of the molecule. None of these control effects are taught or suggested by the cited references. Claim 50, for example, requires inclusion of at least one transport electrode and at least one separate control electrode. Since none of the cited references teach or suggest a cardiac control signal, there is no description of providing a separate control electrode from a transport electrode. The claims discussed above are only examples of dependent claims which are patentable in view of the cited references, and should not be taken as an exhaustive list.

In view of the above comments and amendments, an allowance of all the claims is respectfully awaited. If the Examiner is unable to agree that the claims are patentable, but feels that a telephone conversation can aid in resolving issues in dispute, the Examiner is respectfully requested to contact the undersigned at toll free +1 (877) 428-5468. This number connects directly to our office in Israel. Please note that Israel is 7 hours ahead of Washington and that our work week is Sunday-Thursday.

Respectfully submitted,
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